

Serial No.: 10/728,577

Confirmation No.: 8901

Filed: December 5, 2003

For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS

Remarks

The Office Action dated January 7, 2010 has been received and reviewed. No claims having been amended, cancelled, or added herein, the pending claims remain claims 2-26, 60, and 75-121 (with claims 9, 10, 20, 79-81, 85-87, 95, 96, 102, and 108-121 having been withdrawn from consideration). Reconsideration and withdrawal of the rejections are respectfully requested.

Double Patenting Rejection

Claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, and 103-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 94-117 of copending Application No. 10/728,439, and claims 1-4, 6-35, 37-39, and 45-50 of copending Application No. 10/728,446. Claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, and 103-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-28 of copending Application No. 10/729,114 in view of Asmus (U.S. Patent No. 5,270,358). Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, and 103-107 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that the specification as originally filed does not envision disposing a polymer composition and that Applicants have not identified and the Examiner could not find support in the specification for "polymer composition is disposed thereon," recited in claims 77 and 82.

Applicants submit that "polymer composition is disposed thereon" finds adequate support in the specification generally and specifically at, for example, page 14, line 20 to page 17, line 17. For example, the specification recites "contacting the extruded composition to a rapidly moving plastic web or other suitable substrate" (page 15, lines 9-10), "coating the porous substrate with the composition" (page 15, line 28), and the "composition of the present invention can be coated on the support substrate or impregnated into it, for example" (page 17, lines 15-17).

Therefore, Applicants submit that the language of claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, and 103-107 meets the requirements of 35 U.S.C. §112, first paragraph. Reconsideration and withdrawal of the 35 U.S.C. §112, first paragraph, rejection are requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, and 103-107 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleged that the phrase "polymer composition is disposed thereon," recited in claims 77 and 82, is unclear as to what surface the polymer composition is disposed on. Applicants earnestly disagree.

Claim 77 recites a wound dressing that includes, among other things, "an apertured, liquid permeable substrate and a polymer composition disposed thereon" (emphases added). Applicants submit that the only reasonable construction of this claim language is that the polymer composition is disposed on the substrate.

"[I]f the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant." M.P.E.P. § 2173.02 (emphasis in original). "The test for definiteness under 35 U.S.C. 112, second paragraph, is whether 'those skilled in the art would understand what is claimed when the

claim is read in light of the specification." *Id.* (citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986)) (emphasis added).

Applicants submit that in light of the specification (e.g., the passages cited hereinabove regarding the 35 U.S.C. §112, first paragraph rejection), those skilled in the art would understand what is claimed. Thus, the requirements of 35 U.S.C. §112, second paragraph, are met. Reconsideration and withdrawal of the 35 U.S.C. §112, second paragraph, rejection are requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 2-8, 11-19, 21-26, 60, 75-78, 82-84, 88-94, 97-101, and 103-107 under 35 U.S.C. §103(a) as being unpatentable over Lorenzi et al. (U.S. Patent No. 6,217,889). Applicants traverse this rejection.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness of the rejected claims for at least the reasons provided herein below.

Applicants hereby incorporate by reference Applicants' remarks at pages 14 and 15 in the Amendment and Response submitted October 23, 2009, with the following correction of the record. Applicants misstated in the Amendment and Response submitted October 23, 2009 that "the substrate includes a hydrophobic phase" (emphasis added) which should read as "the composition includes a hydrophobic phase" (emphasis added). Applicants submit that the corrected remarks are sufficient to distinguish Lorenzi et al. Reconsideration and withdrawal of the obviousness rejection are requested. Applicants also provide the following supplemental remarks.

The Examiner alleged, "In the present case, the claims are directed to a product and patentability of the claims is not dependent on how the product is made." (Office Action dated January 7, 2009, page 4.) Applicants submit that the Examiner has misstated or incompletely stated the law. Applicants submit that the Examiner's allegation may be true if and only if the product is recited in a product-by-process claim and the product is the same as or obvious from a product of the prior art. Applicants submit that the Examiner has identified claims 77 and 82 as

product-by-process claims, but has apparently neglected the Examiner's burden of showing that the claimed product is the same as or obvious from a product in the prior art. Although the Examiner bears a lesser burden of proof in making out a *prima facie* case of obviousness of a product-by-process claim (M.P.E.P. §2113), the burden still exists.

Further, Applicants submit that the Examiner must first provide a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, before the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. M.P.E.P. §2113. The Examiner has failed to do this.

Moreover, "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." M.P.E.P. §2113 (citing *In re Garner*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations)). Applicants submit that the Examiner has failed to properly consider the structure implied by the process steps and otherwise recited in the present claims.

For example, Applicants submit that the Examiner cannot ignore that the present claims recite that "at least a portion of the bioactive agent is incorporated within the microparticles."

On this point, at page 8 of the Office Action dated January 7, 2010, the Examiner alleged, "But, the claims are directed to composition/product/article and how the composition is made does not confer patentable distinction over the prior art." Applicants earnestly disagree. The incorporation of bioactive agent within the microparticles is a distinctive structural characteristic. As M.P.E.P. §2113 requires, the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims.

The Examiner also alleged, "Furthermore, there is nothing that says in Lorenzen [sic] that the antiviral agent is not part of the creped non-woven layer or polymeric composition." (Office Action dated January 7, 2010, page 8.)

In evaluating lack of disclosure regarding an obviousness rejection, the Court of Customs and Patent Appeals has stated that "[s]ilence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow." (See *In re Burt and Walter*, 148 U.S.P.Q. 548, 553 (C.C.P.A. 1966).)

Thus, the Examiner's reliance on silence in Lorenzi et al. for disclosing or suggesting "at least a portion of the bioactive agent is incorporated within the microparticles" is clear error.

The Examiner also admitted that "Lorenz [sic] does not specifically teach the sizes of the particles" (Office Action dated January 7, 2010, page 5; emphasis added), "Lorenz is silent in the %amount [sic] of the hydrophilic polymer and the silence is an indication that any amount of the polymer can be used" (Office Action dated January 7, 2010, page 6; emphases added), and "the broad % amount of the polymer particles in amounts of 1-60 wt-% is not inventive over the prior art composition that is silent on the amounts" (Office Action dated January 7, 2010, page 7; emphasis added).

Applicants submit that the Examiner's admitted silence in Lorenzi et al. as to the sizes and amounts of microparticles is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow.

At page 7 of the Office Action dated January 7, 2010, the Examiner alleged that Applicants argued that the composition of Lorenzi et al. is not a wound dressing and that "wound dressing" is an intended use of the composition, and further noted that the composition of Lorenzi et al. includes creped non-woven layer. Applicants are unsure of the Examiner's intent and request clarification. To clarify, Applicants' remarks in the Amendment and Response submitted October 23, 2009 that Lorenzi et al.'s article is a "personal care article suitable for cleansing" and not a wound dressing, was meant to not only distinguish Lorenzi et al. based at least on intended use, but, more importantly, to distinguish Lorenzi et al. based on the characteristics of Lorenzi et al.'s cleansing component, which would be subject to being washed

or dissolved off the substrate, in direct contrast to the presently recited hydrophobic phase, which is antagonistic to, shedding, tending not to combine with, or incapable of dissolving in water.

The Examiner's intent in stating that "in general creped non-woven is used with reference to fibers, which are insoluble in water" (Office Action dated January 7, 2010, page 8, last line of paragraph 19) is also unclear. Clarification is requested.

The Examiner's reasoning at paragraph 21 of page 8 of the Office Action dated January 7, 2010 is also entirely unclear. Clarification is requested. To the extent the paragraph is understood, Applicants provide the following remarks. Each of claims 77 and 82 recites a wound dressing that includes, among other things, a substrate and a polymer composition disposed thereon (i.e., disposed on the substrate), wherein the polymer composition is prepared by a method that includes combining components including, among others, an organic polymer matrix. Thus, the organic polymer matrix is a component of the polymer composition and the polymer composition is disposed on the substrate. The Examiner has apparently relied upon "polyurethane foam and polyesters" for disclosure of the organic polymer matrix (see, e.g., Office Action dated January 7, 2010, page 4, line 2 of paragraph 12 and page 5, lines 8-9 of paragraph 13). However, Applicants maintain that the "polyurethane foam and polyesters (column 4, lines 49-64)" at page 4 of the Office Action dated January 7, 2010 refers, at column 4, lines 49-64 of Lorenzi et al., to materials that form the substrate in Lorenzi et al. For example, materials for "[c]reped nonwoven substrates" (emphasis added) are provided at, for example, Lorenzi et al., column 5, line 53 to column 6, line 52. For disclosure of a substrate, the Examiner appears to rely on the same materials (citing Lorenzi et al., column 4, lines 10-47) that were relied upon for disclosure of the organic polymer matrix. Applicants submit that the rationale underlying the Examiner's obviousness rejection is not sufficient to establish a *prima facie* case.

For at least the reasons provided herein above, Applicants request reconsideration and withdrawal of the obviousness rejection of independent claims 77 and 82. Applicants further request reconsideration and withdrawal of the obviousness rejection of dependent claims 2-8, 11-19, 21-26, 60, 75, 76, 78, 83, 84, 88-94, 97-101, and 103-107 for at least the reasons provided herein and by reason of their own recitations.

For example, claims 24 and 106 recite "wherein the physical foaming agent comprises thermally expandable microspheres." The Examiner alleged that "since microspheres are particles, the microspheres of claims 24 and 106 read on polymer particles in the emulsion Lorenz [sic]." (Office Action dated January 7, 2010, page 5.) Applicants submit that a disclosure in Lorenzi et al. of particles does not disclose or suggest microspheres. As discussed hereinabove, the Examiner has admitted that Lorenzi et al. does not specifically teach the sizes of the particles. Thus, Applicants submit that the Examiner's apparent reliance on silence in Lorenzi et al. regarding particle size is clear error.

For at least the reasons provided herein above, Applicants request reconsideration and withdrawal of the obviousness rejection.

Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Summary

It is respectfully submitted that all of the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 5th day of March 2010.

By:

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